Regulatory adequacy of ecotoxicity data for risk assessment of nanomaterials - the NanoCRED framework

Hartmann, Nanna B.; Ågerstrand, Marlene; Lützhøft, Hans-Christian Holten; Baun, Anders

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Most of these models were assessed in Liguori et al. (2016). Here we further evaluate the methods in regards to their *use-domains*; *types, extent, use and availability of input parameters*; *their output format*; and finally *their potential use and maturity in regard to* meeting the minimum requirements for occupational exposure assessment under *REACH*. We also assess the ability of the models to support SbD (Safe-by-Design) in a NANOREG[2] industry case study on risk innovation governance.

The analyses showed that the models were developed for different purposes and also have different application domains and inclusion criteria. Moreover, the exposure assessment methods and derived risk levels are based on different assumptions and give outputs in different formats. The use of requested input parameters for exposure assessment differs greatly among the tools. Despite, still giving qualitative risk management results, the regulatory readiness is high for Stoffenmanager Nano and NanoSafer, where the information requirements exceed requirements for exposure assessment under REACH and CLP. Only the US Control Banding Nanotool was specifically developed to support safety assessment during innovation. Further harmonization and technical development of the models are required to support SbD approaches (NANOREG[2]) as well as risk innovation governance framework as proposed in the EU H2020 caLIBRAte project (www.nanocalibrate.eu).

References

Liguori B., Hansen S.F., Baun A., and Jensen K.A., 2016. Control banding tools for occupational exposure assessment of nanomaterials — Ready for use in a regulatory context? NanoImpact, 2, 1-17. http://dx.doi.org/10.1016/j.impact.2016.04.002

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Regulatory adequacy of ecotoxicity data for risk assessment of nanomaterials – the NanoCRED framework

Nanna B. Hartmann[1], Marlene Ågerstrand[2], Holten Lützhøft H.C.[1], Anders Baun[1]
[1]Technical University of Denmark, Denmark; [2]Stockholm University, Sweden; abau@env.dtu.dk

Environmental hazard and risk assessment is the foundation for regulatory decisions to protect the environment from unintended adverse effects caused by chemical substances including nanomaterials. The risk assessment process requires relevant and reliable environmental hazard data upon which Predicted No-Effect Concentration (PNEC) values can be estimated - and upon which classification and labelling can be based. In a regulatory context ecotoxicological data is often considered more valid for regulatory use if obtained according to accepted and validated test guidelines, preferably also following Good Laboratory Practice (GLP). It is known, however, that engineered nanomaterials behave very differently in ecotoxicity tests when compared to the 'conventional' soluble chemicals, for which most test guidelines were developed. Therefore non-standard tests, or tests following modified test guidelines, can provide valuable information on nanomaterial hazards and should not per se be considered less reliable. To support expert judgement and facilitate a transparent evaluation of available ecotoxicity data for nanomaterials, we propose twenty criteria for evaluation of ecotoxicity data reliability. These criteria take into account the testing challenges and characterisation requirements associated with nanomaterial ecotoxicity testing. The criteria were developed to be used in combination with the method developed through the 'Criteria for Reporting and Evaluating Ecotoxicity Data (CRED)' project. Combining criteria for evaluation data relevance with criteria for data reliability an overall evaluation of data adequacy can be made. This approach was developed to accommodate all types of nanomaterials, all types of aquatic ecotoxicity studies and support qualitative as well as quantitative data evaluation requirements. Furthermore, it is intended to be practically feasible to implement and directly applicable in European as well as international regulatory frameworks.